UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,575	06/05/2006	Paul Wentworth	1361.027US2	3392

26621 7590 05/16/2008

THE SCRIPPS RESEARCH INSTITUTE
OFFICE OF PATENT COUNSEL, TPC-8
10550 NORTH TORREY PINES ROAD
LA JOLLA, CA 92037

EXAMINER	
ARCHIE, NINA	
ART UNIT	**PAPER NUMBER**
1645	

MAIL DATE	DELIVERY MODE
05/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,575	WENTWORTH ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *1-20,31 and 35-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-30 and 32-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Drawings

2. The drawings in this application have been accepted. No further action by Applicant is required.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Election/Restrictions

4. Applicant's election without traverse of Group II (claims 21-39) is acknowledged.

Claims 1-20, and 35-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group I (claims 1-20), Group III (claim 40-47) and nonelected species of Group II (claims 31 and 35-39), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in 2/8/2008.

Claim Objections

5. Claim 22 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 22 is drawn to a method according to claim 21, wherein the composition further consists of a sensitizer

molecule that can generate singlet oxygen which does not further limit claim 21 which is drawn to a sensitizer molecule that can generate singlet oxygen. Therefore, claim 22 as depending from claim 21, is not further limiting. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 21-23, 25, 29-30, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harmon et al WO/1988/008135 Date October 20, 1988 in view of Hasan et al US Patent No. 7,268,155 Date September 11, 2007 Date Filed May 9, 2002.

Claims 21-23, 25, 29-30, and 33 are drawn to a method of treating a microbial infection in a mammal comprising administering to the mammal an anti-microbial composition consisting essentially of an antibody that can bind to a microbe, a sensitizer molecule that can generate singlet oxygen ($^1O_2$) and a pharmaceutically acceptable carrier.

Harmon et al teach a method of prophylactically treating human patients at risk for bacterial infection, comprising administering to patient a prophylcatically effective amount of human monoclonal antibodies capable of binding an epitope on gram negative bacterial core in a pharmaceutically acceptable carrier, whereby the risk for infection is reduced (see claims).

Hasan et al teach a method of treating a subject, for a disorder characterized by the presence of an unwanted organism such as Salmonella, comprising: administering to the subject a conjugate comprising a polylysine backbone to which is coupled a targeting moiety and a porphyrin photosensitizer such as a hematoporphyrins, wherein the unwanted organism is a bacterium and is located in the oral cavity including throat and tonsil, in the sinus, in the ear, in the nose, in the peritoneal cavity, or on the epidermis (see claims, section “Phostosensitizers”). Thus Hasan et al teach a sensitizer molecule that can generate single oxygen and a microbe associated with staph infection.

It would have been prima facie obvious at the time the invention was made to incorporate a method of treating a bacterial infection comprising administering hematoporphyrins (sensitizer molecule) as taught by Hasan et al into the method of treating a bacterial infection comprising administering an amount of human monoclonal antibodies capable of binding an epitope on gram negative bacterial core as taught by Harmon et al because both teach a method treating a bacterial infection.

7. Claims 21-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harmon et al WO/1988/008135 Date October 20, 1988 in view of Hasan et al US Patent No. 7,268,155 Date September 11, 2007 Date Filed May 9, 2002, Goers et al WO/1986/001720 Date March, 27, 1986, Wentworth et al 2000 PNAS Vol. 97 No. 20

pgs. 10930-10935, and Devanathan et al 1990 Proc. Natl. Acad. Sci. Vol. 87 pgs. 2980-2984.

Claims 21-34 are drawn to a method of treating a microbial infection in a mammal comprising administering to the mammal an anti-microbial composition consisting essentially of an antibody that can bind to a microbe, a sensitizer molecule that can generate singlet oxygen ($^1O_2$) and a pharmaceutically acceptable carrier.

Harmon et al in view of Hasan et al are relied upon as set forth supra.

However Harmon et al in view of Hasan et al does not teach a method, wherein the sensitizer molecule is attached to the antibody, wherein the antibody is a Fab, Fab', $F(ab')_2$, Fv or sFv fragment, wherein the reactive oxygen species is a superoxide radical, or hydrogen peroxide, wherein the reactive oxygen species is ozone, wherein the microbe is Salmonella typhimurium.

Goers et al teach an antibody-therapeutic agent conjugate, comprising: a therapeutic agent capable of acting as a photothermolytic agent , as a photosensitizer to mediate cytotoxic effects attached through a covalent bond to an antibody or antibody fragment to form an antibody-therapeutic agent conjugate, wherein the covalent bond is selectively formed at a site located outside the antigen binding region of the antibody or antibody fragment such as Fab, Fab', $F(ab')_2$. Goers et al teach a photosensitizer is attached to an antibody carrier molecule either by a non-cleavable linker or by direct attachment to the antibody molecule and after delivery of the antibody conjugate to the target site, the photosensitizer is activated by light of the appropriate wavelength and its cytolytic effects on nearby cells are mediated through the generation of singlet oxygen molecules and oxygen free radicals. Goers et al teaches that antibodies directed against any desired target (i.e. antigenic determinants of virus, fungi, bacteria or parasites) may be used as carrier molecules. Goers et al teach that antibodies may be used as carrier molecules, and that monoclonal antibodies offer the advantages of increased specificity for antigen, improved efficiency of the delivery system and ease in production (see claims abstract, Section 3 Summary of Invention paragraphs 1-4, see section 7).

Wentworth et al teach that antibodies to convert molecular oxygen into hydrogen peroxide, thereby effectively linking recognition and killing events (see abstract). Wentworth et al teach that irradiation of antibodies with visible light in the presence of a known photosensitizer of ozone in aqueous solutions, hematoporphyrin, leads to hydrogen peroxide formation (see column 2 paragraph 2). Thus Wentworth et al teach reactive oxygen species is hydrogen peroxide.

Devanathan et al teach fluorescein isothiocyanate-conjugate antibodies can inactivate bacteria such as Salmonella typhimurium. Devanathan et al teach that difluorescein isothiocyanate-conjugate antibodies (DIF-Ab) generate singlet oxygen when illuminated. Devanathan et al teach that singlet oxygen is a potent cytotoxican to Salmonella and E. coli and therefore it is likely that DIF-AB inactivates bacteria by the generation of cytotoxic singlet oxygen.

It would have been prima facie obvious at the time the invention was made to attach a sensitizer molecule to an antibody as taught by Goers et al into the method as taught by Harmon et and Hasan et al because Goers et al and Hasan et al teach antibodies directed against bacteria and because Goers et al teach an antibody conjugated photosensitizer (hematoporphyrin) (therapeutic agent) substantially retain the immunospecificity and immunoreactivity of the original antibody (see Section No. 1).

It would have been prima facie obvious at the time the invention was made to incorporate reactive oxygen species of hydrogen peroxide and ozone as taught by Wentworth et al into the method as taught by Harmon et al and Hasan et al because Wentworth et al teach antibodies to convert molecular oxygen into hydrogen peroxide, thereby effectively linking recognition and killing events.

It would have been prima facie obvious at the time the invention was made a composition consisting essentially of antibody that can bind to a microbe such as Salmonella typhimurium and a sensitizer molecule as taught by Devanathan et al in the method of Harmon et al and Hasan et al because Devanathan et al teach that difluorescein isothiocyanate-conjugate antibodies (DIF-Ab) generates singlet oxygen when illuminated thus inactivating bacteria.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards ad his invention.

8. Claims 21-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to a method of generating a reactive oxygen species to inhibit the growth of a microbe comprising contacting the microbe with (i) an antibody that can bind to the microbe and (ii) a source of singlet oxygen.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is

claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

The claims are so broad that they encompass the detection of every type of microbe; however applicants have not described such a method. The instant specification fails to provide a method where all microbial infections will be treated. The specification fails to teach that every type of microbe can be used within the claimed method. There is no teaching that infection will be treated in parasites, viruses, fungi, yeasts and bacteria. The specification teaches the bactericidal activity of the antibody and source of singlet oxygen within an in vitro assay. Moreover, example IV teaches said activity towards Salmonella, wherein the inhibition of growth occurred during the in vitro portion. There is no written description of any method steps which teach such broadly claimed methods. There are no examples that teach the treatment of each and every type of microorganism. The claims fail to recite the necessary method steps. There are no data showing that the growth of bacteria will be inhibited or ameliorated in every microbial infection. The specification does not provide a substantive description that the claimed method is capable of inhibiting growth in all microbial species. This demonstration is required for the skilled artisan to be able to use the claimed method for its intended purpose. The generic statements drawn to the method do not provide

ample written description for the method. Furthermore, the statements the method being capable of detecting viruses, parasites and fungi does not sufficiently provide ample written description since only bacterial growth is inhibited.

As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claim 21 is a broad generic with respect all possible microbes encompassed by the claims. The possible structural variations are limitless to any class of microorganisms. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of anything other than bacteria. The specification is void of any microorganism which could be used within the instantly claimed method. The specification is limited to bacteria. The written description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention and the claims are rejected.

9. Claims 21-30 and 32-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a microbial infection in a mammal comprising administering to the mammal a particular anti-microbial composition consisting essentially of an antibody that can bind to Salmonella, wherein a sensitizer molecule attached to said antibody that can generate singlet oxygen and, a pharmaceutically acceptable carrier does not reasonably provide enablement for a method of treating a microbial infection in a mammal comprising administering to the mammal a particular anti-microbial composition consisting

essentially of an antibody that can bind to a microbe, a sensitizer molecule that can generate singlet oxygen and a pharmaceutical acceptable carrier. Furthermore, the specification is specifically enabled for an anti-microbial composition consisting essentially of a sensitizer molecule that is attached to antibody, and said antibody that can bind to a microbe. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claimed invention.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims is very broad and the quantity of experimentation required is undue. The product being used to administer to a subject (human or otherwise) stated in claim 21, is overly broad. Claim 1 an antibody that can bind to any microbe and said antibody and a sensitizer in a

composition. Therefore it is hard for one skilled in the art to determine if the composition can be used in treating microbial infections in a mammal. The quantity of experimentation required to practice the invention as claimed would require the de novo determination of accessible target sites, modes of delivery and formulations of the anti-microbial compositions to target appropriate cells and/or tissues in any and/or all organisms/subjects, and further whereby treatment effects are provided for the claimed conditions. Since the specification fails to provide particular guidance for the treatment of microbial infection comprising administering an anti-microbial composition comprising an antibody that can bind to any microbe and said antibody and a sensitizer in a composition to a mammal and since determination of these factors for a particular anti-microbial as consisting essentially of an antibody that can bind to Salmonella, a sensitizer molecule attached to the antibody that can generate singlet oxygen and, a pharmaceutically acceptable carrier nucleotide, it would require undue experimentation to practice the invention over the broad scope as presently claimed.

Nature of the invention/The existence of working examples.

The claims are drawn to method of treating a microbial infection in a mammal comprising administering to the mammal a particular anti-microbial composition consisting essentially of an antibody that can bind to a microbe, a sensitizer molecule that can generate singlet oxygen and a pharmaceutical acceptable carrier.

The specification discloses Examples of antibodies that have the capacity to destroy antigens and Microbiocidal action against Salmonella typhimurium. The specification teaches the bactericidal activity of the antibody and source of singlet oxygen within an in vitro assay. Moreover, example IV teaches said activity towards Salmonella, wherein the inhibition of growth occurred during the in vitro portion (see pp. 45-88).

The specification does not give an example of an antimicrobial composition comprising a sensitizer not attached to an antibody. The specification does not indicate

give examples several different microbes or antibodies that care capable of binding to teach other. The specification does not give an example that any type of antibody can bind to a sensitizer and generate singlet oxygen to kill bacteria or treat all bacterial infections. The examples disclose in the specification contemplate the claimed invention.

The state of the prior art is unpredictable with regard to microbial infection treatments comprising an antimicrobial composition as set forth supra. The state of the art teaches that Hasan et al teach a method of treating a subject, for a disorder characterized by the presence of an unwanted organism such as Salmonella, comprising: administering to the subject a conjugate comprising a polylysine backbone to which is coupled a targeting moiety and a porphyrin photosensitizer such as a hematoporphyrins, wherein the unwanted organism is a bacterium and is located in the oral cavity including throat and tonsil, in the sinus, in the ear, in the nose, in the peritoneal cavity, or on the epidermis (see claims, section “Phostosensitizers”). The art indicates that Goers et al teach an antibody-therapeutic agent conjugate, comprising: a therapeutic agent capable of acting as a photothermolytic agent, as a photosensitizer to mediate cytotoxic effects attached through a covalent bond to an antibody or antibody fragment to form an antibody-therapeutic agent conjugate, wherein the covalent bond is selectively formed at a site located outside the antigen binding region of the antibody or antibody fragment such as Fab, Fab', $F(ab')_2$. Goers et al teach a photosensitizer is attached to an antibody carrier molecule either by a non-cleavable linker or by direct attachment to the antibody molecule and after delivery of the antibody conjugate to the target site, the photosensitizer is activated by light of the appropriate wavelength and its cytolytic effects on nearby cells are mediated through the generation of singlet oxygen molecules and oxygen free radicals. Goers et al teaches that antibodies directed against any desired target (i.e. antigenic determinants of virus, fungi, bacteria or parasites) may be used as carrier molecules. Goers et al teach that antibodies may be used as carrier molecules, and that monoclonal antibodies offer the advantages of increased specificity for antigen, improved efficiency of the delivery system and ease in

production (see claims abstract, Section 3 Summary of Invention paragraphs 1-4, see section 7). The art indicates that Wentworth et al teach that antibodies to convert molecular oxygen into hydrogen peroxide, thereby effectively linking recognition and killing events (see abstract). Wentworth et al teach that irradiation of antibodies with visible light in the presence of a known photosensitizer of ozone in aqueous solutions, hematoporphyrin, leads to hydrogen peroxide formation (see column 2 paragraph 2). Thus Wentworth et al teach reactive oxygen species is hydrogen peroxide. The art indicates that Devanathan et al teach fluorescein isothiocyanate-conjugate antibodies can inactivate bacteria such as Salmonella typhimurium. Devanathan et al teach that difluorescein isothiocyanate-conjugate antibodies (DIF-Ab) generate singlet oxygen when illuminated. Devanathan et al teach that singlet oxygen is a potent cytotoxican to Salmonella and E. coli and therefore it is likely that DIF-AB inactivates bacteria by the generation of cytotoxic singlet oxygen. Additionally, as evidenced by Greenspan et al. (Nature Biotechnology 7: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan et al. recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan et al., an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Moreover, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Accordingly, it follows that the immunoepitopes that can elicit a protective immune response to a given pathogen can only be identified empirically. Therefore the state of the art questions if an antibody can bind to any microbe and sensitizer molecule. Lastly, there is no information on administering the antimicrobial composition as set forth supra to a mammal. For the reasons set forth supra, the state of the art is unpredictable with regard to treating any microbial infection.

G*uidance in the specification*. The specification provides little guidance regarding how the antimicrobial composition as set forth supra is effective when treating microbial infections. Therefore one skilled in the art would not accept on its face the

examples given in the specification as being correlative or representative of the successful treatment in any mammal. The specification as filed fails to provide particular guidance which resolves the known unpredictability in the art associated with effects provided upon administration via any route.

In conclusion, the claimed inventions are not enabled for a method of treating a microbial infection in a mammal comprising administering to the mammal a particular anti-microbial composition consisting essentially of an antibody that can bind to a microbe, a sensitizer molecule that can generate singlet oxygen and a pharmaceutical acceptable carrier. Furthermore, the specification is specifically enabled for an anti-microbial composition consisting essentially of a sensitizer molecule that is attached to antibody, and said antibody that can bind to a microbe. The product being used to administer to a mammal stated in claim 21, is overly broad. The state of the art is unpredictable with the antimicrobial composition and treating microbial infections. As a result, for the reasons discussed above, it would require undue experimentation for one skilled in the art to use the claimed methods.

10. Claims 21, and 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 27-28, dependent claims, recites the limitation “reactive oxygen species” There is insufficient antecedent basis for these limitations in the claims.

Status of the Claims

11. No claims are allowed.

Claims 21-34 are rejected.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina Archie
Examiner
Art Unit 1645

/Nina A Archie/
Examiner, Art Unit 1645
/N. A. A./
Examiner, Art Unit 1645

/Mark Navarro/
Primary Examiner, Art Unit 1645